

K 965208



MiniMed Inc.  
Premarket Notification - 510(k)  
Polyfin Infusion Extension Set  
Model 128

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## Part I. 510(k) Summary

**Submitter:** MiniMed, Inc. 12744 San Fernando Rd., Sylmar, California 91342

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**Name of Device:** Polyfin extension set, models 126 and 128

**Predicate Device:** Polyfin infusion set, models 106, 107, 133

**Description of the New Device:** The new device is a 42 inch or 60 inch length of Polyfin® tubing with Luer connectors at each end. The device attaches at the proximal end to a medication reservoir, such as the MiniMed reservoir, model 103, and at the distal end to an infusion set such as the Polyfin infusion set, model 106. The Polyfin extension set may also be used to administer drugs labeled for intravenous administration from an external pump by attaching the distal end to a "Y-site" or "Heparin lock."

**Intended Use of the New Device:** The Polyfin extension set is intended for use as a fluid delivery set for medication from an external infusion pump.

**Comparison of the Technological Features of the New Device and Predicate Device:** The differences between the subject device and the predicate device are limited to the distal connector and the intended use. The subject device is intended for use as an extension set, *i.e.*, to extend the length of an infusion set such as the predicate device, or to connect the reservoir/infusion pump to a "Y" site or heparin lock.

These modifications do not negatively affect the safety or effectiveness of the device.

Signed,

Terrance H. Gregg  
President and Chief Operating Officer  
MiniMed Inc.

12/23/96  
date

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